

19 to 21% of the lipid component is soy oil and 4–6% soy lecithin. This will provide an omega-6:omega-3 ratio of approximately 1.8:1.

Preferably, in this embodiment, the carbohydrates comprise 36% of the calories. This is equivalent to 135 g/l. In the embodiment, maltodextrin and corn starch are used.

The total calories/nitrogen in this embodiment is approximately 90:1. The total non-protein calories/grams of nitrogen is approximately 67:1. Osmolality will be less than or equal to 500 mOsm/kg H₂O. It is envisioned that the shelf-life of the product will be approximately 12 months.

Pursuant to the present invention, the omega-3 fatty acids as a percent of the total calories of the product will be greater than 2.3%. Anti-inflammatory activity is believed to be achieved at 2.2% to 3% of the calories of the product. Anti-thrombotic and hypolipidemic is also believed to be a benefit of such high levels of omega-3. As set forth above, preferably, fish oil and soy oil are utilized. A number of potential beneficial effects are achieved by using fish oil.

Most typical nutritional products have less than 2.3% of the total calories as omega-3 fatty acids. To this end, the following commercial available products have the following omega-3 fatty acid content (as a % of total calories): IMPACT® 1.6%; IMMUN-AID® 1.0%; PEPTAMEN® VHP 1%; Promote 0.9%; TRAUMACAL® 0.3%; and PEP-TAMEN® 0.2%.

In an embodiment of the present invention, the formulation of the present invention includes at least 3% of the total calories as arginine. Enhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories.

Additionally, in an embodiment, the present invention includes significant amounts of proline. In an embodiment, the proline content is at least 2.0% of the total calories. Proline content as a percent of specific proteins is as follows: gelatin=16.1%; casein=9.6%; whey=5.7%; and soy=5.4%.

Additionally, in an embodiment, the present invention can include significant amounts of cysteine. In an embodiment, the present invention only provides approximately 0.6% of the total calories as cysteine. This is substantially in line with ad-libitum diets. However, the present invention, in an embodiment, provides 0.17% of the total calories as cysteine. Cysteine content of various proteins is as follows: casein=0.3%; total milk products=0.9%; soy protein=1.2%; whey protein=2.0%; and egg white protein=2.5%.

Pursuant to the present invention, non-protein calories/grams of nitrogen (NPC/gN) is determined so as to provide a composition that spares the use of proteins as the calorie source. Patients with severe metabolic stress (trauma, burns) preferably should receive a product with an NPC/gN of less than 100:1 because of their increased protein requirements. Pursuant to the present invention, the formulation provides compositions having less than or equal to 70:1. The weight/nitrogen weight of certain proteins is as follows: arginine 3.11:1; glutamine 5.21:1; casein 6.25:1; protein 6.25:1; whey 6.38:1; proline 8.21:1; branched chain amino acids 8.79:1.

By way of example, and not limitation, examples of formulations of the present invention will now be given.

FORMULA EXAMPLE NO. 1

A liquid, ready-to-use enteral product with protein at 25% of total calories: 87% from partially hydrolyzed casein and 13% from the free amino acid arginine. Carbohydrates would be 35–40% of calories. Lipids comprise 38–42% of

calories, preferably a blend of medium chain triglycerides (50%), fish oil (25%), soy oil and soy lecithin (25% total of both soys). Vitamin and mineral content would meet preferably daily requirements in 1500 calories.

FORMULA EXAMPLE NO. 2

A liquid, ready-to-use enteral product with protein at 25% of total calories: 60% from partially hydrolyzed casein, 20% from partially hydrolyzed whey protein, 15% from the free amino acid arginine and 5% from the free amino acid proline. Carbohydrates would be 35–40% of calories. Lipids comprise 38–42% of calories, preferably a blend of medium chain triglycerides (50%), fish oil (25%), soy oil and soy lecithin (25% total of both soys). Vitamin and mineral content would meet preferably daily requirements in 1500 calories.

By way of example, and not limitation, contemplative examples of the use of the present invention will now be given.

CONTEMPLATIVE EXAMPLE NO. 1

Two hundred patients admitted to intensive care units with moderate to severe trauma are nutritionally supported by the use of tube-fed enteral formulas. Half receive a whole protein based product at 1.0 calories/mL, with protein as 22% of calories (a combination of whole protein and free amino acid arginine), carbohydrates at 50–55% of calories and lipids at 20–25% of calories, with 25% as MCT and the remainder fish oil and sunflower oil. Vitamin and mineral U.S. RDAs met in 1500 calories (1500 mL). Half receive a formula described in this invention: a liquid, ready-to-use enteral product at 1.3–1.5 Kcal/mL with protein at 25% of total calories (87% from partially hydrolyzed casein and 13% from the free amino acid arginine), carbohydrates at 35–40% calories and lipids at 38–42% of calories, with half of the lipid as MCT, 25% fish oil and 25% soy oil and soy lecithin. Vitamin and mineral U.S. RDAs met in 1500 calories (1000 mL).

Many of the patients receiving the whole protein diet were unable to receive the recommended calorie and protein intakes of 2200–2500 calories and 140 grams protein because of intolerance and diarrhea and conflicts with the need to not overhydrate. By comparison, the elemental and calorically dense product described in this invention, it is believed, will be able to deliver 2250 calories and 140 grams protein in 1.5 liters/day with a minimal incidence of intolerance or diarrhea. When using APACHE scoring to predict outcomes, the patients fed the enteral diet described in this invention will, it is believed, have a shorter average length of stay and fewer inflammatory complications than would have been expected based on experiences with whole protein-based diets which contain less than 2.3% of calories as a mixture of omega-3 fatty acids (linolenic, EPA and DHA).

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

We claim:

1. A method for providing nutrition to a trauma, burn or post-surgery patient comprising the step of enterally administering to the patient a therapeutically effective amount of a composition comprising: